PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 05 FB 11 E	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/EP2005/050414	International filing date *(day/month/year)* 01.02.2005	Priority date *(day/month/year)* 06.02.2004
International Patent Classification (IPC) or national classification and IPC INV. A23L1/30 A23L1/308 A61P1/04 A61K31/19 A61K31/715 A61K31/733 A61K9/20 A61K9/00		
Applicant COSMO TECHNOLOGIES LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19.09.2005	02.06.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Tallgren, A Telephone No. +31 70 340-3933

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2005/050414

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-12 as originally filed

   Claims, Numbers

   1-22 received on 13.12.2005 with letter of 13.12.2005

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-22
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-22
Industrial applicability (IA)	Yes:	Claims	1-22
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

1. The amended claims 1 and 12 fulfill the criteria set by article 34(2)b and are therefore accepted (based to old claims 1, 5 and 13, 17 respectively).

2. ITEM V

2.1. The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: WO 02/02102 A (COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION; BIRD, AN) 10 January 2002 (2002-01-10)
D2: WO 95/13801 A (COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH OR; ANISSON, GEOFFREY;) 26 May 1995 (1995-05-26)
D3: WO 01/02016 A (COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION; BIRD, AN) 11 January 2001 (2001-01-11)

2.2. INVENTIVE STEP OBJECTIONS

D1 describes a composition containing short-chain fatty acid (acetate, propionate and butyrate), fiber or oligosaccharide (fructo-saccharides, inulin (page 41 lines 30-35)) and excipient/carrier (the fiber may act as excipient and vice verca). The short-chain fatty acids are covalently bonded to the carrier (inulin, pectin), but are released in the colon. This falls under the scope of compositions of claims 1 and 12. Additionally a controlled release coating to be released in colon. Use for the treatment of intestinal disorders and inflammation (claims 1,9,12,15,25, examples 11-13,16, page 5 line 17- page 7 line 4). Consequently, the subject matter of claims 1-22 is considered as being not inventive in view of D1 (Art 33 (3) PCT).

D2 describes a composition containing short-chain fatty acid (acetate, propionate and butyrate) and several carriers/excipients (fiber (inulin, pectin, maltodextrin), the fiber may act as excipient or as a fiber). The short-chain fatty acids are covalently bonded to the carrier (inulin, pectin), but are released in the colon. This falls under the scope of compositions of claims 1 and 12. Additionally a controlled release coating to be released in colon. Use for the treatment of intestinal disorders and inflammation (claims 1,2,5,19-

21,24-26,29, example 8,11). Consequently, the subject matter of claims 1-22 is considered as being not inventive in view of D2 (Art 33 (3) PCT).

D3 describes a composition containing short-chain fatty acid (butyric acid), fiber (fructo-oligosaccharide (inulin) and several carriers/excipients (fiber (inulin, pectin, maltodextrin), the fiber may act as excipient or as a fiber (table 13)). The short-chain fatty acids are covalently bonded to the carrier (inulin, pectin), but are released in the colon. This falls under the scope of compositions of claims 1 and 12. Use for the treatment of intestinal disorders in colon. (claims 1,6,7,16,20,39, example 8, page 26 lines 21-29). Consequently, the subject matter of claims 1-9,12-19 is considered as being not inventive in view of D3 (Art 33 (3) PCT).

None of the claimed compositions or uses are considered to be inventive in view of D1-D3 (Art 33(3) PCT). Having regard to the claimed compositions or uses and the prior art known (D1-D3), it is considered that the man skilled in the art would regard these compositions or uses of the present invention (as far as novel) as an obvious alternative to those known. Therefore, unless an unexpected effect for the present compositions or uses (as far as novel) over the prior art disclosure from D1-D3 can be demonstrated, these compositions, uses or methods do not fulfill the requirements of Art 33(3) PCT.

CLAIMS

(110)

1. Oral pharmaceutical or dietary composition containing at least one short-chain fatty acid or salt, ester and/or amide thereof, in combination with a complex sugar and/or dietary fibre in which the complex sugar and/or dietary fibre is selected from inulin, pectin, dextrin, maltodextrin or derivatives thereof and with one or more pharmacologically acceptable excipients.

2. Composition according to Claim 1 in which the short-chain fatty acid is a linear or branched C_1-C_5 monocarboxylic organic acid.

3. Composition according to Claim 1 in which the short-chain fatty acid is selected from: acetic acid, propionic acid, butyric acid, and isovaleric acid, preferably butyric acid.

4. Composition according to Claim 1 in which the short-chain fatty acid is butyric acid.

5. Composition according to any one of the preceding claims in which a quantity of from 5 to 50% by weight of the short-chain fatty acid is included.

6. Composition according to any one of the preceding claims in which a quantity of from 10 to 30% by weight of the short-chain fatty acid is included.

7. Composition according to any one of the preceding claims in which a quantity of from 5 to 50% by weight of the soluble dietary fibre is included.

8. Composition according to any one of the preceding claims in which a quantity of from 10 to 30% by weight of the soluble dietary fibre is included.

9. Oral pharmaceutical or dietary composition according to any one of the preceding claims in tablet, capsule, granule and/or micro-granule form.

10. Oral pharmaceutical or dietary composition according to any one of the preceding claims, characterized in that it is an intestinal controlled-release composition.

11. Oral pharmaceutical or dietary composition according to any one of the preceding claims, containing a gastro-resistant coating.

12. Use of a short-chain fatty acid in combination with a soluble dietary fibre in which the complex sugar and/or dietary fibre is selected from inulin, pectin, dextrin, maltodextrin or derivatives thereof for the preparation of a pharmaceutical or dietary composition for the treatment of intestinal disorders, inflammatory disorders, and pathological conditions of the intestinal mucous membrane and for the preventive or limiting treatment of intestinal neoplasia.

13. Use according to Claim 13 in which the short-chain fatty acid is a linear or branched C_1-C_5 monocarboxylic organic acid.

14. Use according to any one of the preceding claims in which the short-chain fatty acid is selected from: acetic acid, propionic acid, butyric acid, and isovaleric acid, preferably butyric acid.

15. Use according to any one of the preceding claims in which the short-chain fatty acid is butyric acid.

16. Use according to any one of the preceding claims in which a quantity of from 5 to 50% by weight of the short-chain fatty acid is included.

17. Use according to any one of the preceding claims in which a quantity of from 10 to 30% by weight of the short-chain fatty acid is included.

18. Use according to any one of the preceding claims in which a quantity of from 5 to 50% by weight of the soluble dietary fibre is included.

19. Use according to any one of the preceding claims in which a quantity of from 10 to 30% by weight of the soluble dietary fibre is included.

20. Use according to any one of the preceding claims in tablet, capsule, granule and/or micro-granule form.

21. Use according to any one of the preceding claims, characterized by intestinal controlled release.

22. Use according to any one of the preceding claims, including a gastro-resistant coating.